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APPLICATION NUMBER 08/782,590	FILING DATE 01/13/97	FIRST NAMED APPLICANT ROSE	ATTORNEY DOCKET NO. 18M1/0523
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18M1/0523

EXAMINER LAWSON, G
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ART UNIT 1806	PAPER NUMBER
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05/23/97

DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on Application Filed 1/13/97

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-87 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-87 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☒ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-39 and 61-63 are drawn to a method for treating heterogeneous populations of cancer cells with two bispecific reagents, classified in Class 514, subclass 2.

Group II. Claims 40-42 are drawn to a method for treating heterogeneous populations of cancer cells with two bispecific reagents and a third therapeutic agent, classified in Class 514, subclass 2 and Class 424, subclass 130.1.

Group III. Claims 43-46 are drawn to a method for treating heterogeneous populations of cancer cells with two bispecific reagents and a third bispecific reagent, classified in Class 514, subclass 2.

Group IV. Claims 47-50 are drawn to a method for treating heterogeneous populations of cells with two bispecific reagents and a fourth bispecific reagent classified in Class 514, subclass 2.

Group V. Claims 51-54 are drawn to a method for treating heterogeneous populations of cells with two bispecific reagents and a fifth bispecific reagent classified in Class 514, subclass 2.

Group VI. Claim 55 is drawn to a method for treating heterogeneous populations of cells with two bispecific reagents and a sixth bispecific reagent classified in Class 514, subclass 2.

Group VII. Claim 56 is drawn to a method for treating heterogeneous populations of cells with two bispecific reagents and a seventh bispecific reagent classified in Class 514, subclass 2.

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Group VIII. Claim 57 is drawn to a method for treating heterogeneous populations of cells with two bispecific reagents and a eighth bispecific reagent classified in Class 514, subclass 2.

Group XIV. Claim 58 is drawn to a method for treating heterogeneous populations of cells with two bispecific reagents and a ninth bispecific reagent classified in Class 514, subclass 2.

Group X. Claim 59 is drawn to a method for treating heterogeneous populations of cells with two bispecific reagents and a tenth bispecific reagent classified in Class 514, subclass 2.

Group XI. Claim 60 is drawn to a method for treating heterogeneous populations of cells with two bispecific reagents and a eleventh bispecific reagent classified in Class 514, subclass 2.

Group XII. Claims 64-66 and 68 are drawn to a method for treating heterogeneous populations of cells with two bispecific reagents by administering a killing process classified in Class 514, subclass 2.

Group XIII. Claim 67 is drawn to a method for treating heterogeneous populations of cells with two bispecific reagents by administering a killing process which alters the hormonal status classified in Class 514, subclass 2.

Group XIV. Claim 69-83 are drawn to a composition of a therapeutic agent and a bispecific reagent classified in Class 530, subclass 402.

Group XV. Claim 84 is drawn to a bispecific reagent, classified in Class 530, subclass 402.

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2. The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I-XIII are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

Inventions XIV and XV represent chemically distinct products, obtained by and used in different methods.

The inventions of Groups XIV and I-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the bispecific reagent and the therapeutic agent of the composition as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)], for example, affinity chromatography.

The inventions of Groups XV and I-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (i) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the bispecific reagent as claimed can be

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used in a materially different process of using that product [see *MPEP* § 806.05(h)], for example, affinity chromatography.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. Group I is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language, the phrase "at least" in the last paragraph, page 45 is assumed, for examination purposes, to mean one of the group of the first, second and neo-antigenic epitopes of the first extra-cellular precipitate.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the first extra-cellular precipitate has: (a) a first antigenic epitope being an epitope which is an integral part of the structure of the first extra-cellular precipitate; (b) a second antigenic epitope; and (c) a neo-antigenic third epitope (see p. 45).

5. Group I is further subject to election of a single disclosed species.

Because of the indefinite nature of claim language, the phrase "at least" in paragraph 3 of p. 46 is assumed, for examination purposes, to mean one of the group of the first, second and neo-antigenic epitopes of the first extra-cellular precipitate.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the second bispecific reagent binds to: (a) a first antigenic epitope being an epitope which is an

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integral part of the structure of the first extra-cellular precipitate; (b) a second antigenic epitope; and (c) a neo-antigenic third epitope (see p. 46).

Species (a), (b) or (c) will be examined with the corresponding elected species of (a), (b) or (c) of Section 3 cited above.

6. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the first enzyme moiety of the bispecific reagent is: (a) beta lactamase (claim 2); (b) penicillinase (claim 3); (c) glycosidase (claim 4).

7. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the 1st therapeutic agent is: (a) a soluble agent selected from a group of agents (claim 5); and (b) a soluble moiety and an insoluble moiety (claim 18).

8. Group I is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language, the phrase "at least" is assumed, for examination purposes, to mean one of the group of species (a)-(e) cited below.

Claims 1 and 5 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the first therapeutic agent is a soluble agent and is an organic chemical comprising at least one of: (a) peptides, including opio-melanins; (b) carbohydrates including

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cellulose, chitosan and chitin; (c) proteoglycans; (d) synthetic polymers; and (e) indoxyl compounds having molecular positions 1-7.

9. Group I is further subject to election of a single disclosed species in that species (b) of claim 5 is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language and the recitation of the phrase "at least" in the preamble of claim 5, it is assumed for examination purposes that the carbohydrate is selected from the group of species (a), (b) and (c) as disclosed below:

Claims 1 and 5 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the first therapeutic agent is a carbohydrate selected from the group of: (a) cellulose; (b) chitosan; and (c) chitin. Species (a), (b) or (c) will be examined if species (b) of Section 7 is elected.

10. Group I is further subject to election of a single disclosed species.

Claims 1 and 5 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby indoxyl compounds have molecular positions 1-7 and: (a) contain compounds attached at position 3 (claim 13); and (b) contain compounds attached at position 4-7 (claims 14-17 and 61). Species (a) or (b) will be examined if species (e) of Section 7 is elected.

11. Group I is further subject to election of a single disclosed species. Because of the indefinite nature of the claim language, it is assumed for

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examination purposes that the phrase "at least" means one of the group of species (a)-(c) recited below.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the first therapeutic agent is an indoxyl compound selected from the group of: (a) indoxyl-penicillin; (b) indoxyl-cephalosporin; (c) indoxyl-glycosides. Claim 13 will be examined if species (a), claim 13, is elected in Section 9.

12. Group I is further subject to election of a single disclosed species.

Claim 14 is subject to election of a single disclosed species and will be examined if species (b), claims 14-17 and 61 is elected in Section 9.

Because of the indefinite nature of the claim language, the phrase "at least" is assumed to mean, for examination purposes, one of the group of species (a)-(d) recited below.

Claim 14 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the indoxyl compounds include a substance attached to at least one of positions: (a) 4; (b) 5; (c) 6; and (d) 7.

13. Group I is further subject to election of a single disclosed species.

Claims 15-17 and 61 will be examined if the species (b), claims 14-17 and 61, is elected from Section 9 and species (b) is elected from claim 14, Section 11.

Claims 1, 5, and 14 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the



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indoxyl compounds include a substance attached to one of a group of positions whereby: (a) phenyl compounds are attached at position 5 (claim 15); whereby benzyloxy compounds are attached at position 5 (claim 16); whereby 5,5-bi-indoxyls are attached at position 5 (claim 17 and 61).

14. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the 1st therapeutic agent is: (a) inherently cell impermeant (claim 6); and (b) chemically altered by the attachment of a cell-impermeant chemical which causes the additional therapeutic agent to be cell impermeant (claims 7 and 8).

15. Group I is further subject to election of a single disclosed species.

Claims 1, 7 and 8 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the cell-impermeant chemical includes one of: (a) thiol; and (b) anionic materials. The limitation of "materials having a molecular weight greater than 1000 daltons" will be examined with elected species (a) or (b). Claims 7 and 8 will be examined if species (b) of Section 13 is elected.

16. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby: the second enzyme moiety is: (a) beta lactamase (claim 19); (b) penicillinase (claim 20); (c) glycosidase (claim 21); (d) chondroitinase ABC).

17. Group I is further subject to election of a single disclosed species.

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Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the targeting agent moiety of the second bispecific reagent has a substantial affinity for: (a) the first antigenic epitope of the first extracellular precipitate (claim 23); (b) the second antigenic epitope of the first extracellular precipitate (claim 24); (c) the neo-antigenic third epitope of the first extra-cellular precipitate (claim 25). Species (a), (b) or (c) will be examined with the corresponding elected species of Section 4.

18. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the additional therapeutic agent: (a) is a soluble radioactive toxic agent selected from a group of agents (claims 26 and 30); (b) has a soluble and insoluble moiety (claim 39).

19. Group I is further subject to election of a single disclosed species.

Claim 1 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the additional therapeutic agent is: (a) inherently cell impermeant (claim 27); and (b) chemically altered by the attachment of a cell-impermeant chemical which causes the additional therapeutic agent to be cell impermeant (claims 28 and 29).

20. Group I is further subject to election of a single disclosed species.

Claims 1, 28 and 29 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the cell-

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impermeant chemical includes one of: (a) thiol; and (b) anionic materials. The limitation of "materials having a molecular weight greater than 1000 daltons will be examined with elected species (a) or (b). Claims 28 and 29 will be examined if species (b) of Section 18 is elected.

21. Group I is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language, the phrase "at least" is assumed to mean, for examination purposes, one of the group of species (a)-(e) listed below.

Claims 1 and 26 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the additional therapeutic agent is a soluble radioactive toxic agent is an organic chemical selected from the group of (a) peptides including opio-melanins; (b) carbohydrates, including cellulose, chitosan and chitin; (c) proteoglycans; (d) synthetic polymers; (e) indoxyl compounds having molecular positions 1-7.

22. Group I is further subject to election of a single disclosed species as claim 26, species (b) is subject to election of a single disclosed species.

Because of the indefinite nature of the claim language and the recitation of the phrase "at least" in the preamble, it is assumed for examination purposes that the carbohydrate is one selected from the group of species (a)-(c) cited below.

Claims 1 and 26 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the additional therapeutic agent is a carbohydrate selected from the group of: (a) cellulose; (b)

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chitosan; and (c) chitin. Species (a), (b), or (c) of Section 21 will be examined if species (b) of Section 20 is elected.

23. Group I is further subject to election of a single disclosed species.

Claims 1 and 26 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby indoxyl compounds have molecular positions 1-7 and: (a) contain compounds attached at position 3 (claim 34); and (b) contain compounds attached at position 4-7 (claims 35-38 and 62). Species (a) or (b) will be examined if species (e) of Section 20 is elected.

24. Group I is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language, it is assumed for examination purposes that the phrase "at least" means one of the group of species (a)-(c) recited below.

Claim 34 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the first therapeutic agent is an indoxyl compound selected from the group of: (a) indoxyl-penicillin; (b) indoxyl-cephalosporin; (c) indoxyl-glycosides. claim 34 will be examined if species (a), claim 34, is elected in Section 22.

25. Group I is further subject to election of a single disclosed species.

Claim 35 is subject to election of a single disclosed species and will be examined if species (b), claims 35-38 and 62, is elected in Section 22.

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Because of the indefinite nature of the claim language, the phrase "at least" is assumed to mean, for examination purposes, one of the group of species (a)-(d) recited below.

Claim 35 is generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the indoxyl compounds include a substance to at one of positions: (a) 4; (b) 5; (c) 6; and (d) 7.

26. Group I is further subject to election of a single disclosed species.

Claims 36-38 and 62 will be examined if the species (b), claim 35-38 and 62, is elected from Section 22 and species (b) is elected from Section 24.

Claims 1, 26, and 35 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the indoxyl compounds include a substance attached to one of a group of positions whereby: (a) phenyl compounds are attached at position 5 (claim 36); whereby benzyloxy compounds are attached at position 5 (claim 37); whereby 5,5-bi-indoxyls are attached at position 5 (claim 38 and 62).

27. Group I is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language, it is assumed for examination purposes that the oxidation of the new form in claim 12 does not occur through a "natural" process.

Claims 1 and 9 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the first therapeutic agent is inherently soluble and is converted to an insoluble extra-cellular precipitate whereby: (a) the new form is insoluble (claim 10); (b) the

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new form is a soluble intermediate which is converted naturally into a precipitate (claim 11); (c) the new form is oxidized into a soluble intermediate molecule that spontaneously dimerizes and then precipitates (claim 12).

28. Group I is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language, it is assumed for examination purposes that the oxidation of the new form in claim 33 does not occur through a "natural" process.

Claims 1 and 30 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the additional therapeutic agent is inherently a soluble molecule which is converted by a second enzyme moiety into a new form which is: (a) insoluble (claim 31); (b) a soluble intermediate (claim 32); (c) is rapidly oxidized, the oxidized soluble intermediate molecule spontaneously being dimerized (claim 33).

29. Group III is further subject to election of a single disclosed species.

Claims 1 and 43 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the third bispecific reagent has a substantial affinity for: (a) the first antigenic epitope of the first extracellular precipitate (claim 44); (b) the second antigenic epitope of the first extracellular precipitate (claim 45); (c) the neo-antigenic third epitope of the first extra-cellular precipitate (claim 46).

30. Group IV is further subject to election of a single disclosed species.

Claims 1 and 47 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the fourth

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bispecific reagent has a substantial affinity for: (a) the first antigenic epitope of the first extracellular precipitate (claim 48); (b) the second antigenic epitope of the first extracellular precipitate (claim 49); (c) the neo-antigenic third epitope of the first extra-cellular precipitate (claim 50).

31. Group V is further subject to election of a single disclosed species.

Claims 1 and 51 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby the fourth bispecific reagent has a substantial affinity for: (a) the first antigenic epitope of the first extracellular precipitate (claim 52); (b) the second antigenic epitope of the first extracellular precipitate (claim 53); (c) the neo-antigenic third epitope of the first extra-cellular precipitate (claim 54).

32. Group XII is further subject to election of a single disclosed species.

Claims 1 and 64 are generic to a plurality of disclosed patentably distinct species comprising the method of the instant invention whereby a cell killing process is administered and includes: (a) a process of administering a cytotoxic agent capable of selectively killing cells (claims 65 and 68); (b) a non-cytotoxic agent capable of selectively killing cells (claim 66).

33. Group XIV is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language, the phrase "at least" is assumed to mean, for examination purposes, one of the group of species (a)-(c) cited below.

Claim 69 is generic to a plurality of patentably distinct species comprising a composition of a first therapeutic agent and a first bispecific reagent whereby

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the first therapeutic agent is a soluble agent and is an organic chemical comprising at least one of: (a) peptides, including opio-melanins; (b) carbohydrates including cellulose, chitosan and chitin; (c) proteoglycans; (d) synthetic polymers; and (e) indoxl compounds having molecular positions 1-7.

34. Group XIV is further subject to election of a single disclosed species in that species (b) of Section 33, claim 69, is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language and the recitation of the phrase "at least" in the preamble of the claim, the carbohydrate is assumed to be one of the group of species (a)-(c) cited below.

Claim 69 is generic to a plurality of disclosed patentably distinct species whereby the first therapeutic agent is a carbohydrate selected from the group of: (a) cellulose; (b) chitosan; and (c) chitin. Species (a), (b) or (c) will be examined if species (b) of Section 33 is elected.

35. Group XIV is further subject to election of a single disclosed species.

Claims 69 is generic to a plurality of disclosed patentably distinct species whereby indoxyl compounds have molecular positions 1-7 and: (a) contain compounds attached at position 3 (claim 76); and (b) contain compounds attached at position 4-7 (claims 77-81). Species (a) or (b) will be examined if species (e) of Section 33 is elected.

36. Group XIV is further subject to election of a single disclosed species.



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Because of the indefinite nature of the claim language, it is assumed for examination purposes that the phrase "at least" means one of the group of species (a)-(c) recited below.

Claim 76 is generic to a plurality of disclosed patentably distinct species whereby the first therapeutic agent is an indoxyl compound selected from the group of: (a) indoxyl-penicillin; (b) indoxyl-cephalosporin; (c) indoxyl-glycosides. Claim 76 will be examined if species (a), claim 76, is elected in Section 34.

37. Group XIV is further subject to election of a single disclosed species.

Claim 77 is subject to election of a single disclosed species and will be examined if species (b), claims 77-81 is elected in Section 34.

Because of the indefinite nature of the claim language, the phrase "at least" is assumed to mean, for examination purposes, one of the group of species (a)-(d) recited below.

Claim 77 is generic to a plurality of disclosed patentably distinct species whereby the indoxyl compounds include a substance to at one of positions: (a) 4; (b) 5; (c) 6; and (d) 7.

38. Group XIV is further subject to election of a single disclosed species.

Claims 78-81 will be examined if the species (b), claim 77-81, is elected from Section 34 and species (b) is elected from Section 36.

Claims 69 and 77 are generic to a plurality of disclosed patentably distinct species whereby the indoxyl compounds include a substance attached to one of a group of positions whereby: (a) phenyl compounds are attached at position 5

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(claim 15); whereby benzyloxy compounds are attached at position 5 (claim 16); whereby 5,5-bi-indoxyls are attached at position 5 (claim 17 and 61).

39. Group XIV is further subject to election of a single disclosed species.

Claim 69 is further subject to election of a single disclosed species.

Because of the indefinite nature of the claim language, it has been assumed for examination purposes that the phrase "at least" means one of a first, second and neo-antigenic third epitope.

Claim 69 is generic to a plurality of disclosed patentably distinct species whereby the first extra-cellular precipitate has: (a) a first antigenic epitope being an epitope which is an integral part of the structure of the first extra-cellular precipitate; (b) a second antigenic epitope; and (c) a neo-antigenic third epitope (see p. 46).

40. Group XIV is further subject to election of a single disclosed species.

Claim 69 is generic to a plurality of disclosed patentably distinct species whereby the 1st therapeutic agent is: (a) inherently cell impermeant (claim 70); and (b) chemically altered by the attachment of a cell-impermeant chemical which causes the additional therapeutic agent to be cell impermeant (claims 71 and 72).

41. Group XIV is further subject to election of a single disclosed species.

Claim 72 is generic to a plurality of disclosed patentably distinct species comprising a composition of a first bispecific reagent and a first therapeutic agent whereby the cell-impermeant chemical includes one of: (a) thiol; and (b) anionic materials. The limitation of "materials having a molecular weight

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greater than 1000 daltons" will be examined with elected species (a) or (b).

Claim 72 will be examined if species (b) of Section 39 is elected.

42. Group XIV is further subject to election of a single disclosed species.

Claim 69 is generic to a plurality of disclosed patentably distinct species whereby the additional therapeutic agent: (a) is inherently soluble (claims 73); (b) has a soluble and insoluble moiety (claim 82).

43. Group XIV is further subject to election of a single disclosed species.

Due to the indefinite nature of the claim language, it is assumed that the oxidation of the soluble intermediate is not "naturally" oxidized.

If species (a) claim 73, inherently soluble molecule is elected from Section 41, claims 74 or 75 will be examined.

Claims 69 and 73 are generic to a plurality of disclosed patentably distinct species comprising a composition of a first bispecific reagent and a first therapeutic reagent whereby the first therapeutic agent is: (a) converted into a soluble intermediate molecule which is naturally converted into the first extra-cellular precipitate (claim 74); and (b) oxidized to form a dimer which precipitates (claim 75).

44. Group XV is subject to further subject to election of a single disclosed species.

Claim 84 is generic to a plurality of patentably distinct species comprising a bispecific reagent whereby the first enzyme moiety is: (a) beta lactamase (claim 85); (b) penicillinase (claim 86); and (c) glycosidase (87).

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45. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

46. A telephone call was made to John McQuillan (212-599-2245), on May 8, 1997 to request an oral election to the above restriction requirement, but did not result in an election being made.

47. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

48. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

49. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 308-305-2181.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached at (703) 308-2731. The fax phone number for this Art Unit is (703) 308-4065.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan Ungar

May 12, 1996

A handwritten signature in black ink, appearing to read 'LILA FEISEE', with a large, sweeping flourish extending to the right.

**LILA FEISEE  
SUPERVISORY PATENT EXAMINER  
GROUP 1800**